Genesis Biosystems

SEP 1 2 2008

510(k) Summary of Safety and Effectiveness

Accelawave System

510(k) Number K082484

Applicant:	Genesis Biosystems
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Date prepared:	04 / 23 / 2008
Device Trade Name:	Accelawave System
Common Name:	Intense Pulsed Light (IPL)
Classification Name:	Laser Surgical Instrument 21 C.F.R § 878.4810
Product Classification:	Class II device
Product Code:	ONF

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Legally Marketed Predicate Device: The Accelawave System is substantially equivalent in terms of technological characteristics, performance, intended use, indications for use and operator interface to;

- Chromogenex (K053324)
- Sciton (K032460)
- Lumenis (K020839)

System Description: The Accelawave is an Intense Pulsed Light-based medical device utilizing xenon flash lamp technology to illuminate the dermis to offer light based therapies as listed in the indications of use. The Accelawave emits *light at 420nm to 1200nm via a 15mm x 45mm treatment area at a repetition rate equal to or less than 0.5Hz (operator selective).
*Light is delivered to the skin surface while a water-cooled heat transfer network cools the contacting surfaces and the epidermis.

Performance Standards: The device complies with the European Medical Directive 93/42/EEC concerning medical devices, and will comply with voluntary standards UL60601-1:1996 when marketed in the U.S.

Indications for use: Indications for Use for Fitzpatrick skin types (I to VI)

- The removal of unwanted hair and to effect stable long-term or *permanent hair reduction.
  Permanent hair reduction is defined as a long-term stable reduction in the number of hairs re-growing after a treatment regimen.
- The treatment of moderate inflammatory acne vulgaris
- The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions including warts, scars, and striae.

- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, erythema of rosacea, angiomas, and spider angiomas, poikiloderma of civatte, leg veins and venous malformations.

The integrated thermal cooling is indicated for use in cooling the epidermis at the treatment site prior to, during, and after treatment in general aesthetic dermatologic and plastic surgery procedures.

- Reduce pain during and/or with light treatment (via partial anesthesia from cooling)
- Reduce discomfort during and/or associated with light treatment
- Minimize thermal injury, including thermal necrosis, to non-target skin and skin structures during and/or associated with light treatment, thus reducing possible complications such as scabbing, scarring, hyper – and/or hypopigmentation
- Allow the use of higher light fluences for light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions)
- Reduce potential side effects of light or laser treatments (such as for hair removal and the treatment of vascular or pigmented lesions)

Conclusion: The Accelawave System is substantially equivalent to its predicate devices, based upon predicate similarities. The skin is treated in the same manner as the predicate devices, Intense Pulsed Light and dermal cooling.

Similarities / Differences	Lumenis Vasoulite	Sciton BBL	Chromolight
Output Spectrum Characteristics	Similar	Similar	Similar
Output Pulse Characteristics	Similar, Programmable	Similar, Programmable	Similar, Programmable
Treatment Parameters	Similar, Programmable	Similar, Programmable	Similar
Skin Cooling/Epidermal Cooling	Cold Gel vs. Cold Contact Cooling (difference)	Similar Cold Contact Cooling	none

Side Effects: In extreme cases, effects from treatment can include excessively red patches in the shape of the applicator head and blistering. If this occurs the tissue should be cooled and cared for as would normally be the case with burns to the skin, i.e. do not burst any blister formation, keep clean and covered until healed.

If blisters form, they are usually intra-epidermal in nature and heal without scarring. Inappropriate management of blisters during the healing stage will increase the chance of scarring.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Genesis Biosystems, Inc.
% Underwriters Laboratories, Inc.
Mr. Casey Conry
Senior Project Engineer
1285 Walt Whitman Road
Melville, New York 11747

AUG 26 2011

Re: K082484
Trade/Device Name: Accelawave System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: ONF
Dated: August 26, 2008
Received: August 28, 2008

Dear Mr. Conry:

This letter corrects our substantially equivalent letter of September 12, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other

Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known): K082484

Device Name: Accelawave System

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082484

Indications for Use for Fitzpatrick skin types (I to VI)

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Indications for Use

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Device Name: Accelawave System

Indications For Use:

Indications and Filters vs. Skin Types

CONDITIONS	FILTER SETTINGS and WAVELENGTH RANGE	SKIN TYPES I	II	III	IV	V	VI
Hair (course)		640-1200	640-1200	640-1200	640-1200	690-1200	690-1200
Hair (fine)		640-1200	640-1200	640-1200	640-1200	690-1200	690-1200
Acne Vulgaris		420-1200	420-1200	420-1200	420-1200	510-1200	N/A
Pigmented Epidermal Lesions							
a) Dyschromia		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
b) Hyperpigmentation		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
c) Melasma		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
d) Ephelides		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
Cutaneous Lesions							
a) Warts		420-1200	420-1200	420-1200	420-1200	420-1200	N/A
b) Scars		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
c) Striae		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
Cutaneous Vascular Lesions							
a) Port Wine Stain (Child)		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
b) Port Wine Stain (Adult)		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
c) Hemangiomas		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
d) Telangiectasias		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
e) Rosacea		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
f) Angiomas		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
g) Spider Angiomas		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
h) Poikiloderma		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
i) Venous Malformations		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
Leg Veins							
a) Small		510-1200	510-1200	510-1200	560-1200	560-1200	N/A
b) Medium		560-1200	560-1200	560-1200	560-1200	560-1200	N/A
c) Large		560-1200	560-1200	560-1200	560-1200	N/A	N/A

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for MXM
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K082484

MNM